



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

NOV 20 1998 3379 '98 NOV 25 P2:23

Mr. John Swope  
Swope Company  
20801 SE Lansing Lane  
Boring, Oregon 97009

Dear Mr. Swope:

This is in response to your letter of November 17, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Swope Company is making the following statement, among others, for the product:

**Glucosamine Sulfate**

“Supplements of glucosamine taken continuously have restored range of motion and reduced pain by rebuilding cartilage in joints”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, mitigate, or cure diseases, namely, degenerative joint disorders and pain. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 238

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Dorsey)

f/t:HFS-456:rjm:11/20/98:docname:62394.adv:disc33

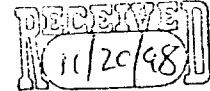
# SWOPE COMPANY

20801 SE LANSING LANE  
BORING, OR 97009  
PH (503) 658-7065 FAX (503) 658-3149

60234

November 17, 1998

Secretary of Health and Human Services  
c/o Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, D. C. 20204



To the Official Listed Above:

Notice is provided under Section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act of the label used on a dietary supplement which will be distributed interstate beginning next week.

Swope Company, an Oregon corporation, is beginning to distribute this product.

The address is: 20801 SE Lansing Lane  
Boring, OR 97009

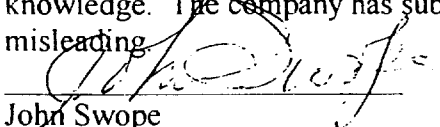
We also do business as Better Living and as Better Living through Nutrition.

The text of the statement being made follows.

<p>Each Capsule Provides: Glucosamine 500 mg Supplied as 663 mg Glucosamine Sulfate Direction: Adults take 1 capsule 3 times daily. Tamper resistant package for your protection. Contains no additives. BETTER LIVING THROUGH NUTRITION GRESHAM, OR 97030</p>	<p><b>GLUCOSAMINE SULFATE</b>  NO SODIUM  NATURALLY DERIVED FULL STRENGTH FORMULATION  CONTENTS: 90 CAPSULES</p>	<p>Glucosamine is the molecule your body uses to build and repair cartilage. With age the body's glucosamine level can decrease, resulting in less cushioning at the joints. Supplements of glucos- amine taken continuously have restored range of motion and reduced pain by rebuilding cartilage in joints. These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.</p>
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The dietary supplement referred to is glucosamine sulfate.  
There is no brand name at this point.

I certify that the above statements are complete and accurate to the best of my  
knowledge. The company has substantiation that the statement made is truthful and not  
misleading.

  
John Swope  
President